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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,260	02/29/2000	Dasa Lipovsek	50036/021003	1893

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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/515,260	LIPOVSEK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Maury Audet	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-44 and 51-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-44 and 51-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
       If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
       a) ☐ All    b) ☐ Some    \* c) ☐ None of:  
           1. ☐ Certified copies of the priority documents have been received.  
           2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
           3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
       \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
       a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9, 15</u> | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### **Change of Art Unit Designation**

1. Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1653 to Art Unit 1654. To aid in matching papers in this application, all further correspondence regarding this application should be directed to **Group Art Unit 1654**.

### **Reply to Examiner's Action**

2. Applicant's Reply to Office Action, filed December 15, 2002, Paper No. 16, is acknowledged.

### **Status of the Claims**

3. Claims 1-67 were originally filed in the present application. Claims 40-67 (Group 3), in response to restriction, were elected without traverse in Paper No. 7. Claims 40-67 were then rejected in Paper No. 8. Claims 40-42, 51, 52, 57, 59-61, and 63-64 were then amended in Paper No. 11, leaving claims 40-44 and 51-68 pending. Claims 40-44 and 51-68 were then rejected in Paper No. 14. Claims 40, 41, and 59 were then twice amended in Paper No. 16, leaving claims 40-44 and 51-68 under examination. All of the claims stand rejected under 35 U.S.C. § 112, 2<sup>nd</sup> ¶; claims 41, 43, and 44 also stand rejected under 35 U.S.C. § 112, 1<sup>st</sup> ¶.

This application contains claims 1-39, and 45-50 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### **Information Disclosure Statement**

4. The Information Disclosure Statement filed October 21, 2002 (Paper No. 12) has been considered. Additionally, the Information Disclosure Statement filed September 6, 2001 (Paper

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No. 9), which Applicant noted had not been initialed and returned has also been considered.

Initialed copies of Form PTO-1449 in accordance with MPEP § 609 are attached.

**Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> ¶**

5. The rejection of claims 40 and 42 as to what sequences are considered “randomized” in claims 40-44 and 51-68 is withdrawn in light of the amendment of the claims. The inclusion of claims 40 and 42 in this rejection was inadvertent.

The rejection of all claims 40-44 and 51-68, based on Figure 3 of Mead et al., is maintained. Applicant’s arguments have been fully considered but they are not persuasive. Applicant relies for support from Dickenson et al. (1994), that there is only one known sequence of and module of the tenth module. However, Dickenson et al., in section (g), states that “[I]n the absence of crystal structures of any other FNIII modules, the structure-based alignment in Figure 8 can be used as a comparative tool to predict structurally equivalent residues in other FNIII modules”. Further down, it is described that “connecting segments protrude from the ends of the III-10 module, sequences in these loops are accessible for intra- . . . interactions”. In particular, the fact that Dickenson leaves open the possibility of intra modular interactions, it cannot be stated with certainty that other tenth module sequences or substitutions exist. Alternatively, the rejection may be overcome by Applicant amending the claims to be limited to the specific structure of the amino acid sequence of the tenth module described within the specification, namely that identified in Figure 3.

The rejection of claim 59, under 35 U.S.C. § 112, 2<sup>nd</sup> ¶, is maintained. Applicant’s arguments have been fully considered but they are not persuasive. As Applicant cites on page 9, lines 1-2, “randomized” can mean one OR MORE amino acid alterations relative to a template

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(such as the claimed tenth module) sequence. The amendment to include the language above, nevertheless leaves the claim indefinite as to which amino acid alteration(s) constitute the invention.

The rejection of claims 40, 42, 44, 51, 53-56, and 68, under 35 U.S.C. § 112, 2<sup>nd</sup> is withdrawn. The claims were rejected based on claim 40 and its dependent claims lacking essential steps. Independent claim 40 has been amended, to include the omitted steps recommended by the previous examiner: the steps involved in obtaining a protein with at least three randomized loops from a library of proteins having only one or two randomized loops. Specifically, the language “said scaffold-based proteins having at least three randomized loops” was added to overcome the rejection.

**Rejection under 35 U.S.C. § 112, 1<sup>st</sup> ¶**

6. The rejection of claims 41, 43, and 44 under 35 U.S.C. § 112, 1<sup>st</sup> ¶, as lacking enablement, is withdrawn. Applicant’s amendment of claims 41 (and thus depending claims 43 and 44), along with 40 and 59, have overcome the rejection. The rejection is withdrawn.

**New Rejection**

**Rejection under 35 U.S.C. § 112, 1<sup>st</sup> ¶**

7. Claims 40-44, and 51-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, Applicant is asked to point out in the specification, the specific locations of any “three randomized loops” on the scaffold-based

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proteins and evidence of the binding of any "three randomized loops" to a compound not bound by the human 10Fn3 sequence.

#### Conclusion

8. No claims are allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA

March 7, 2003

  
**BRENDA BRUMBACK**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**